Summary of the
ELAB PBMS Subcommittee Teleconference
March 6, 1997

The Performance Based Measurement Systems (PBMS) subcommittee of the Environmental Laboratory Advisory Board (ELAB) convened by teleconference on March 6, 1997, at 1 pm. The meeting was led by its chair, Dr. Kathy Hillig of BASF Corporation. *The purpose of this meeting was to continue revision of draft recommendations to ELAB.*

A list of action items is provided in Attachment A. A list of participants is given in Attachment B. The prepared agenda included:

1. Discussion of previously drafted recommendations 3 & 4 concerning reference methods;
   - All Offices must ensure that reference methods exist that are capable of meeting any regulatory requirement, and
   - All reference methods must be validated in the appropriate matrix and that validation must be documented.
2. Definitions for performance based methods and measurement systems; and
3. What needs to happen to make Performance Based Measurement Systems (PBMS) acceptable to all stakeholders.

A memorandum from David Friedman (3/4/97) outlining PBMS implications, and implementation issues, was also distributed to subcommittee members.

MISCELLANEOUS ITEMS

Dr. Hillig asked for additions and corrections to the minutes of January 30, 1997. There were none. Mr. Larry Lafleur will forward the electronic version of the minutes for posting on EPA's TTN/NELAC web site.

RECOMMENDATON #3

To begin discussion it was asserted that EPA should specify Measurement Quality Objectives (MQOs) rather than reference methods when it promulgates regulations. Further discussion of this draft recommendation resulted in the following wording:

> "ELAB recommends that before EPA promulgates a regulation, it must demonstrate and document that Measurement Quality Objectives (MQOs) are achievable using available measurement technology"

Mr.David Friedman discussed the EMMC's use of the term "Performance Based Measurement Systems" (PBMS) with respect to the term "Performance Based Methods" (PBMs). He noted that under PBMS, any method (including EPA methods) are acceptable to EPA when it can be demonstrated to meet EPA's MQOs. He noted that this should not be confused with PBMs, since no particular measurement method is associated with it.

Discussion of the term "reference method" (the legally required "right way" to make a

measurement) ensued. Hence, under PBMS, a reference method is not meaningful; EPA must simply demonstrate that it is possible to achieve the promulgated MQOs. EPA may note the methods it has found that are capable of meeting the MQOs, without stipulating a required method. This would occur as a matter of documentation, not requiring approval (i.e., demonstration of equivalency to a reference method).

The possibility that the method-derived quality parameter, rather than health-based or other scientifically based information, may be the source of the MQO was acknowledged. It was also acknowledged that current laws and regulations may need to be changed to allow for this approach.

RECOMMENDATION #4

The "demonstration" of the achievability of MQOs should be applicable in the matrix of interest, for the measurement method of interest. Measurement in a non-similar matrix, including water, is not seen by members of the subcommittee as a valid demonstration. This is seen as a major regulatory implementation issue, irrespective of whether a "reference system" or PBMS is adopted.

Based on extensive discussion, it was agreed to reword the recommendation to read:

> "EPA must demonstrate that any new or revised regulatory measurement requirements are achievable on samples that represent the same level of analytical challenge as the matrix for which the regulation is intended. (Ideally, this would be samples of the actual matrix to be monitored, as defined by the regulation.)"

The issue of clear definition of the term "matrix" is a critical issue in this discussion. Mr. Friedman offered to share with this subcommittee the definition currently being used by EPA's Environmental Monitoring Management Council (EMMC). They are provided as Attachment C.

ADDITIONAL ISSUES

Subcommittee members discussed the charter of this ELAB subcommittee, agreeing that PBMS should be implemented. However, it was acknowledged that there is concern over the acceptance of PBMS among stakeholders. It was also agreed that a focus on <u>how</u> to effectively implement PBMS may also address more fundamental concerns. For example, under the highly flexible environment envisioned for PBMS, auditing will need to be carefully addressed, as will other issues.

It was noted that this subcommittee has been asked to address both issues for ELAB.

NEXT MEETING

The next teleconference of this subcommittee is tentatively scheduled for Thursday, April 3, 1997

1 - 3 pm. EST. The remainder of today's agenda will be addressed at that time.

Attachment A

ACTION ITEMS
ELAB PBM Subcommittee Teleconference
March 6, 1997

Action	Date Completed
Larry LaFleur will forward minutes of the January 30 meeting to Gene Tatsch for processing to post on the TTN/NELAC website.	

Attachment B

LIST OF PARTICIPANTS
ELAB PBM Subcommittee Teleconference
March 6, 1997

Name	Affiliation	Telephones
Kathy Hillig, Chair	BASF Corporation	T: 313/246-6334 F: 313/246-5226 E:
Mike Conlon (absent)	Lab Strategy Group	T: 703/913-1314 F: 703/913-1314 E:
David Friedman (invited)	USEPA	T: 202/260-3535 F: 202/260-4346 E: friedman.david@epamail.epa.gov
Larry LaFleur	NCASI	T: 541/752-8801 F: 541/752-8806 E:llafleur@wcrc-ncasi.org
Cynthia Lee (absent)	Analytical Services Laboratory	T: 502/962-6400 F: 502/962-6411 E:
Jeanne Mourrain, Designated Federal Officer	USEPA, NERL-Research Triangle Park	T: 919/541-1120 F: 919/541-4101 E: mourrain.jeanne@epamail.epa.gov
Tony Pagliaro (absent)	ACIL	T: 202/887-5872 F: 202/887-0021 E: acil@ix.netcom.com
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LEVELS OF METHOD PERFORMANCE DOCUMENTATION

Purpose and Goals

The purpose of the method performance documentation categorization scheme is to provide a simple system for documenting the amount of validation data available on specific EPA test methods. The goal is to give potential users an indication of how confident they can be in a method's published precision, bias and method sensitivity values and use this information to help select which EPA method is most suitable for their needs.

The intention is for the documentation codes to be included in EPA methods indices such as the Environmental Monitoring Methods Index (EMMI). For example, an analyst analyzing a sediment sample for polynuclear aromatic compounds could look at an index such as EMMI and find several potentially appropriate methods. By looking at the documentation code, the analyst can quickly determine to which level the available methods have been validated and more easily make a decision about which method she/he wants to use.

This scheme is not meant to be used as an approval process nor does it prescribe how to validate a method for a particular purpose. The only stipulation for a method being rated is that the procedures used for measuring precision, bias and method sensitivity be approved by the program for which the method is being developed. Procedures for measuring precision, bias and method sensitivity are not provided; it is only stipulated that the procedures must be approved by the program.

Definition of Levels

The system is comprised of three levels. Level 1 has the least stringent documentation requirements and Level 3 has the most stringent requirements. The higher the level the more complete the validation process.

Level 1 Validation

Data are available in the EMMC data base or the regulatory docket that documents the precision, bias, method sensitivity and dynamic range of the method based on a single laboratory evaluation using at least one example of a suitable matrix.

Level 2 Validation

Data are available in the EMMC data base or the regulatory docket that documents the precision, bias, method sensitivity and dynamic range of the method based on the evaluation of at least one example of a suitable matrix by a minimum of two laboratories.

Level 3 Validation

Data are available in the EMMC data base or the regulatory docket that documents sufficient information for a multi-laboratory, multi-matrix validation study that satisfies the methods approval needs of national standard setting bodies such as the Association of Official Analytical

Chemists (AOAC) or the American Society for Testing and Materials (ASTM). These organizations require that the validation data must include data from at least seven laboratories and that the materials used to validate the method must include a variety of samples whose characteristics encompass the variety of materials that the method is expected to encounter in routine use.

NA This classification scheme is not considered as applicable to a method of this type.

NR No determination has been made as to the level of documentation that is currently available for this method.

Definition of Terms

Bias:

The systematic or persistent distortion of a measurement process which deprives the result of representativeness (i.e., the expected sample measurement is different than the sample's true value.) The bias of a measurement method is due to the systematic error inherent in the method and may be described as the degree to which the method yields results that are consistently different from the sample's true value.

Dynamic Range:

The range of sample concentrations over which the method will yield data of acceptable quality.

Matrix:

A specific subset of a medium (e.g., surface water, drinking water, kaolinite) in which the analyte of interest may be contained. Matrices may be defined/differentiated by their behavior: samples of the same or similar matrix are expected to behave the same or similarly with respect to the procedure(s) employed on them.

Method Sensitivity:

The characterization of a method's performance in terms such as detection limit, quantitation limit, dynamic range, etc. by an EPA (or other commonly recognized) method validation protocol.

Precision:

The degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.

Validated method:

A method which has been determined to meet certain performance criteria for sampling and/or measurement operations.

Validation:

The process of substantiating specified performance criteria. Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. (ISO 8402)